Patient registry coordination

Vivien Vass

Patient Registry Coordinator

Project preparation and data collection

Centre for Translational Medicine

Mária Földi

Patient Registry Coordinator

Data analysis and report

Centre for Translational Medicine

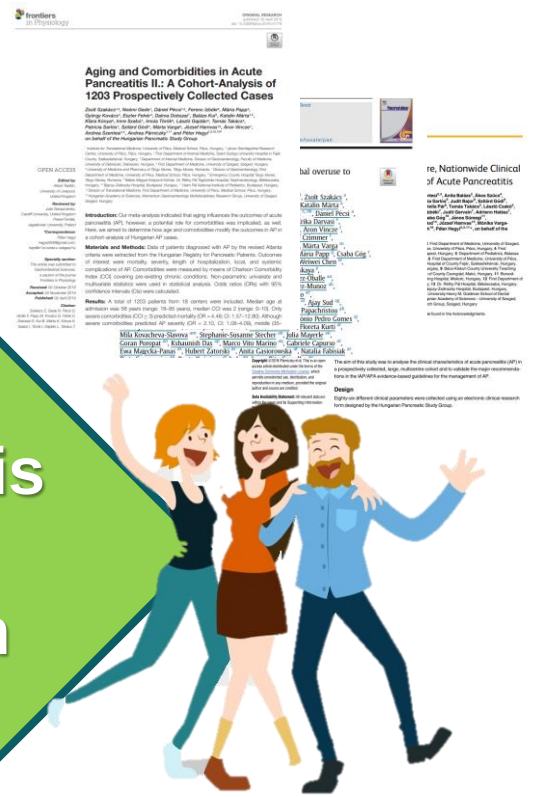
Pécs, 2020.10.12.

What does the registry coordinator do?

Launch a new project

Data collection

Data analysis and publication



- Support project conduct, logistics, and track project status
- Develop and maintain relationships with external physicians and scientists, study sites/research institutions to initiate and facilitate projects.
- Monitor data collection
- Maintain policies and procedures (SOPs) related to clinical registries and studies, which guarantee high quality and efficient operation
- Support publication and improve quality

Launch a new registry

1. Question & answers

2. Case Report Form (CRF)

3. Ethical approval

4. eCRF (electronic case report form)

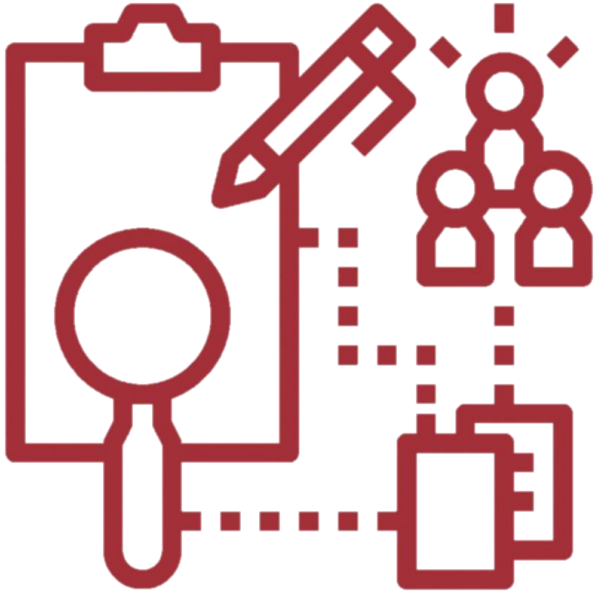
5. User’s guide

6. Local training to data managers

7. Organize patient involvement locally

Data collection

1. Data recording



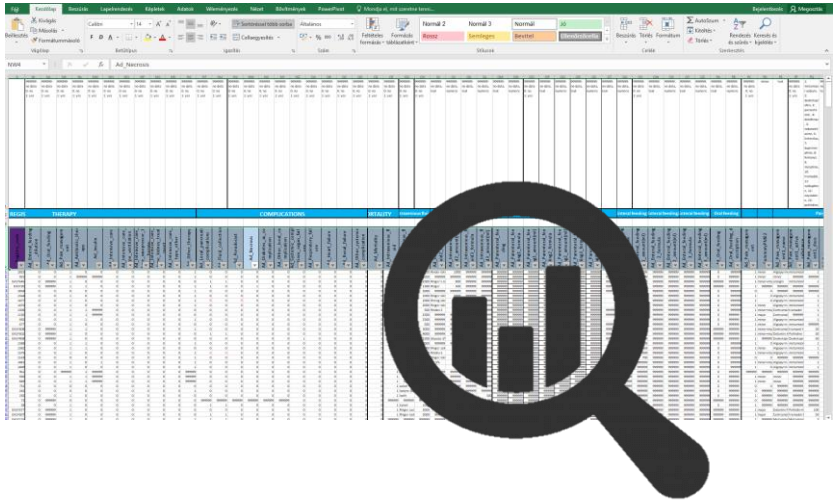
3. Recruitment of new centers

2. Quality assurance

Registry data retrieval

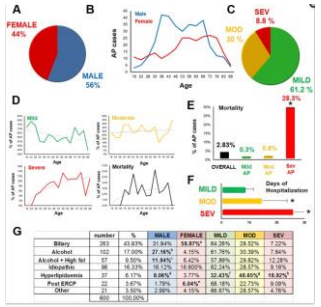
Professional consultation

Data retriaval



Data analysis

Data cleaning



Basic description and exploratory analyses

Analysis plan

Manuscript writing

Ongoing registries

Gastroenterology

- Pancreas Registry
- ERCP Registry
- Celiac Disease Registry
- NAFLD Registry
- Wilson's Disease Registry
- Achalasia Registry
- IBD Registry
- Esophageal Cancer Registry
- Cystic Fibrosis Related Pancreatic Disorders Registry
- Gastrointestinal Bleeding Registry
- Decompensated Liver Research and IT System Registry
- Pancreatic Cystic Neoplasms Registry

Cardiology

- Cardiomyopathy Registry
- Acute Heart Failure Registry
- Registry for Atrial Fibrillation and Flutter Patients
- QT Registry, Understanding the characteristics of QT-variability and cardiovascular autonomic neuropathy in diabetes

Traumatology

- SupraCondylaer Humerus Fracture Registry

Endocrinology

- Acromegaly Registry
- Chest Neuroendocrine Tumor Registry

Infectology

- COVID-19 Registry

Registries in progress with ethical approval

Gastroenterology

- Autoimmune Liver Disease Registry
- Walled-off Pancreas Necrosis Registry

Dentistry, Oral and Maxillofacial Surgery

- Registry of Oral Potentially Malignant Disorders
- Cleft Lip and Palate Registry

Otorhinolaryngology

- Sudden Sensorineural Hearing Loss Registry

Registries in progress without ethical approval

Gastroenterology
- APPLE-F (Analysis of Pediatric Pancreatitis Follow-up)
- Polyposis Registry
- PEG Registry

Cardiology
- Reconstruction based on Coronary Registry with the use of 3D modeling
- Reperfusion and Arrhythmia Registry
- CTO Registry, Morphological Assessment and Reopening of coronary Vessels in CTO

Neurology
- Muscular Dystrophy Registry
- NMOSD-MOGAD Registry, Neuromyelitis Optica spectrum disorder and Mog Antibody Disease

Infectology
- Clostridioides difficile Registry

Hematology
- Multiple myeloma registry

Dentistry, Oral and Maxillofacial Surgery
- Temporomandibular Disorders Registry

Otorhinolaryngology
- HPV associated head and neck squamous cell carcinoma

Endocrinology
- Graves-Basedow Disease Registry

Immunology-rheumatology
- Systemic sclerosis associated interstitial pneumonitis registry
- HUNOS Registry HUNgarian adult Onset Still's disease registry
- HUNTER Registry, HUNgarian enTERopathic arthritis registry
- HURA Registry, Hungarian Rheumatoid Arthritis registry
- Neuropsychiatric lupus registry

Thank you for your attention!

University of Pécs
Centre for TRANSLATIONAL MEDICINE

SZÉCHENYI 2020
HUNGARIAN GOVERNMENT
European Union
European Social Fund
INVESTING IN YOUR FUTURE

The decision about the registry, aims and international research

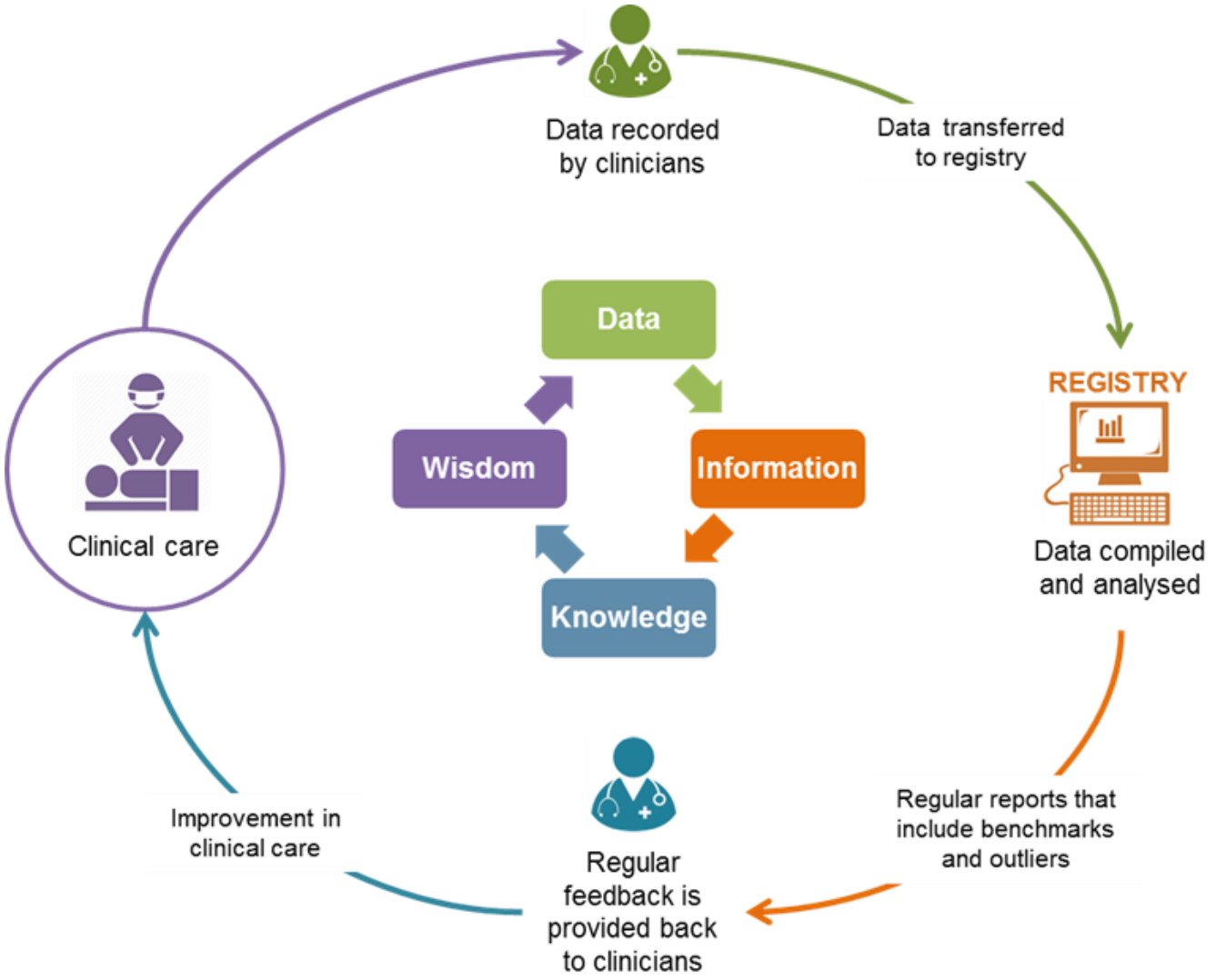
Klementina Ocskay
Pécs, Hungary

Definition

A patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s).

Gliklich RE, Dreyer NA: Registries for Evaluating Patient Registries: A User's Guide: AHRQ publication No. 07-EHC001. Rockville, MD. April 2007

Clinical improvement cycle



Uses

The registry is <u>SUITABLE</u> for analyzing

- epidemiology
- risk factors
- course of the disease
- associations

The registry is <u>SUITABLE</u> for

- establishing protocols
- calculating sample size for clinical trials

The registry is <u>NOT SUITABLE</u> for discovering

- causality
- differences between therapies or interventions

Strengths and limitations

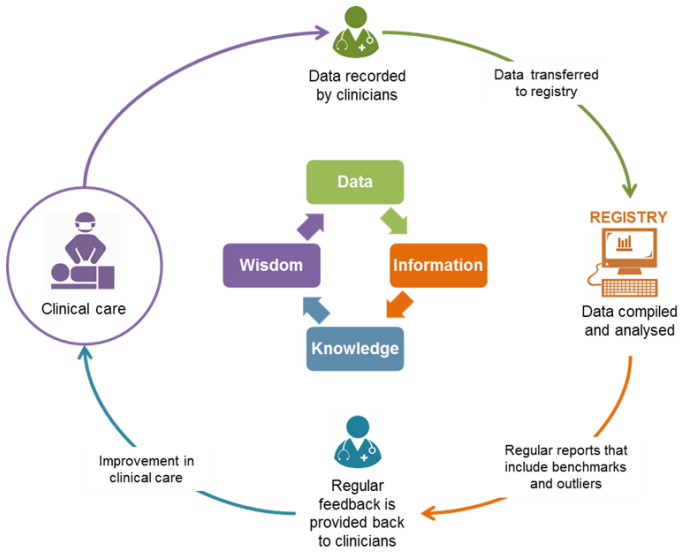
TABLE 1 Strengths and limitations of registry-based studies

Strengths	Limitations
Longitudinal data of large sample size	Assessment or treatment criteria may be not uniform—potential for selection bias
Track the natural history of the disease over time	Patients seen in diverse centres/countries
Track the long-term effectiveness and safety of treatments	Lack of data verification
Enable time-to-event analysis	May not have complete data/follow-up
Allow subset analyses	Patients are not monitored as rigorously as in randomized controlled studies—the rate of some events may be underestimated
Essential information source for rare diseases	Data are collected anonymously—avoid duplicate records on same patient
Provide generalizable evidence	No control population
Provide evidence of the effectiveness of treatments in the real world	Potential for industry influence on analytical methods
Generate new hypotheses for further investigation	

Galluccio F et al. Registries in systemic sclerosis: a worldwide experience. Rheumatology (Oxford). 2011 Jan;50(1):60-8.

Benefits

- Providing data fo researchers
- Demographic of patients – trends, influencing factors?
- Current treatment landscape – areas of concern and progress
- Preparing clinical trials – e.g. sample size calculation
- Connecting physicians
- Data-driven care



Pitfalls

- **Internal** vs **external validity**
- **Missing data**
- **Bias and confoundig factors**
- **Design is not suitable** to test hypothesis
- Only **associations** can be drawn

Evidence from registries

Management of Familial Adenomatous Polyposis in Children and Adolescents: Position Paper From the ESPGHAN Polyposis Working Group

*Warren Hyer, †Shlomi Cohen, ‡Thomas Attard, §Victor Vila-Miravet, ||Corina Pienar, ¶Marcus Auth, #Seth Septer, *Jackie Hawkins, **Carol Durno, and *Andrew Latchford

Should children and families with familial adenomatous polyposis be managed within a polyposis registry?

Recommendation 9:
Where feasible, children and adolescents should be enrolled into their regional or national polyposis registry (depending on local and national provision) to coordinate their care. Polyposis registries improve outcome for FAP patients by improving the rate of diagnosis of FAP and reduce the incidence of CRC.
(weak recommendation, moderate-quality evidence, consensus agreement 100%)

Management of Juvenile Polyposis Syndrome in Children and Adolescents: A Position Paper From the ESPGHAN Polyposis Working Group

*Shlomi Cohen, †Warren Hyer, ‡§Emmanuel Mas, ||Marcus Auth, ¶Thomas M. Attard, #Johannes Spalinger, †Andrew Latchford, and **Carol Durno

TABLE 7. Areas requiring research in the field of juvenile polyposis

Does a specific paediatric colonic juvenile polyposis phenotype predict colorectal cancer risk in adulthood?
Are children and adolescents with 4 or 5 metachronous juvenile polyps and no identifiable mutation at risk of gastrointestinal malignancies in adulthood?
Chemoprevention in juvenile polyposis including collaboration with basic scientists to better understand underlying mechanisms.
Well characterized juvenile polyposis kindreds with multiple affected members and no identifiable mutation require genomic evaluation in order to identify additional genes involved in juvenile polyposis phenotypes.

First steps

- What is/are your/our **aim(s)**?
- Is registry the **best way** to acheive it/them?
- **Registries in this field?** (International or national?)
- EBM **guidelines, position papers**
- **Cohort analyses**
- Is it an **acute or chronic** registry?

Structure

TRANSLATIONAL MEDICINE Registries

TRANSLATIONAL MEDICINE

ACUTE PANCREATITIS | FORM B Further days | Patient Questionnaire

PANCREAS REGISTRIES – PANCREATIC STUDY GROUP

1. Patient personal details

RegisterAP No:
Doctor code:

Name: .....
Pediatric pancreatitis: yes / no / no data
Admission date: .....
Last day of treatment: .....

2. Status

Blood pressure (Hgmm):.....
Body weight (kg):.....
Respiratory rate (/minute):.....
Oxygen saturation (%): .....
Abdominal tenderness: yes / no / no data
Jaundice: yes / no / no data

Heart rate (/minute):.....
Body height (cm):.....
Body temperature (axillary, °C): .....
Previous O2 therapy: yes / no / no data
Abdominal guarding: yes / no / no data

3. Lab results (if any)

Amylase increased more than 3x yes / no / no data

Lipase increased more that 3x yes / no / no data

Amylase (U/l)	
Lipase (U/l)	
White blood cell (WBC) count (G/l)	
Red blood cell (RBC) count (T/l)	
Hemoglobin (g/l) Conversion: mmol/l	
Hematocrit (%)	
Thrombocyte (G/l)	
Glucose (mmol/l) Conversion: mg/dL	
Blood urea nitrogen (mmol/l) Conversion: mg/dL	
Creatinine (umol/l) Conversion: mg/dL	
eGFR	
C-reactive protein (mg/l)	
ASAT/GOT (U/l)	
Lactate dehydrogenase LDH (U/l)	
Calcium (mmol/l)	

Only arterial blood gas parameters should be registered. Please indicate the measuring condition of blood gas parameters
Measuring conditional of blood gas parameters: N/A / room air / 100% O_2
Previous O2 therapy: yes / no / no data

Sodium (mmol/l)	
Potassium (mmol/l)	

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HUNGARIAN PANCREATIC STUDY GROUP
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Registry director: Andrea Szentesi Tel: +36 70 293 7537 e-mail: szentesiai@gmail.com
Address: Korányi fasor 8-10., 6720 Szeged, Hungary

FORM A Admission fo | FORM B Follow-up | FORM C Complication form | FORM E Endoscopic form | FORM I Images form | FORM P Pregnancy form

CROHN'S DIS | CROHN'S DI | CROHN'S DISEASE | CROHN'S DISEA | CROHN'S DISE | CROHN'S DISEASE

IBD REGISTRY – CROHN'S AND COLITIS STUDY GROUP

Country:
City:
Hospital:
Doctor:

Patient personal details

Insurance number:.....
Name:.....
Date of birth:.....
Contact number:.....

Pregnancy
Was the patient pregnant before? yes/ no
If yes, the number of conceivings:.....(piece)
the number of live births:.....(piece)

Pregnancy: yes/ no
if yes, the date of pregnancy:.....(year, month)

the way of getting pregnant: spontaneous / assisted reproduction
number of pregnancy weeks:..... (weeks)

Disease activity:
At conception: active/ in remission CDAI:.....points
First trimester: active/ in remission CDAI:..... points
Second trimester: active/ in remission CDAI:..... points
Third trimester: active/ in remission CDAI:..... points

Live birth: yes/ no
Premature birth: yes/ no
Caesarean operation: yes/ no
The weight of the newborn baby:.....(gramm)
APGAR of the newborn baby (0. minute): ...../10
APGAR of the newborn baby (10. minute): ...../10
Congenital Developmental Disorder: yes/ no
If yes, type of the Congenital Developmental Disorder:.....

Abortion: yes/ no
If yes: artificial/ spontaneous

Ectopic pregnancy: yes/ no

Shared data structure

Alcohol consumption: yes / no / no data

if yes: frequency: occasionally/monthly/weekly/daily
amount (g/occassion):.....
For how many years? .....
Total alcohol consumption in the last 2 weeks: .....

if not: Did the patient drink alcohol earlier? yes/no/ no data
if yes: frequency: occasionally/monthly/weekly/daily
amount (g/occasion):.....
For how many years?.....
How long ago did the patient stop drinking alcohol?.....

Guide for estimation of the amount:
1 dl beer (4.5 vol. %) = ~3.5 g alcohol
1 dl wine (12.5 vol. %) = ~10 g alcohol
1 dl hard drink (50 vol. %) = ~40 g alcohol

Smoking: yes / no/ no data

if yes: amount (cigarettes/day):.....
How many years ago have you started? .....
Pack year (automatically calculated) .....

if not: Did the patient smoke earlier? yes/no/ no data
if yes: amount (cigarettes/day):.....
For how many years?.....
Pack year: (automatically calculated) .....
How long ago did the patient stop smoking? .....

Biobank

Am J Gastroenterol. 2017 Dec;112(12):1896-1898. doi: 10.1038/ajg.2017.393.

Novel PRSS1 Mutation p.P17T Validates Pathogenic Relevance of CTRC-Mediated Processing of the Trypsinogen Activation Peptide in Chronic Pancreatitis.

Németh BC[1,2], Szücs Á[3], Hegyi P[4,5], Sahin-Tóth M[1].

page: www.elsevier.com/locate/pan

Pancreas. 2019 Feb;48(2):e12-e14. doi: 10.1097/MPA.0000000000001214.

Evaluation of the Pathogenic Significance of the Novel p.T58M Chymotrypsin C Variant in Recurrent Acute Pancreatitis.

Németh BC[1], Hegyi P, Takács T.

ate secreting anion exchanger

Eszter Hegyi, MD,† Andrea Geisz, PhD,*‡ Miklós Sahin-Tóth, MD, PhD,‡ Monique H. M. Derikx, MD,‡ Balázs Csaba Németh, MD, PhD,‡ Anita Balázs, MD,* István Hritz, MD, PhD,* Ferenc Izbéki, MD, PhD,§ Adrienn Halász, MD,§ Andrea Párniczky, MD,|| Tamás Takács, MD, PhD, DSc,**

egyi [a, c], István Hritz [a], László Czakó [a], aba Németh [d], Judit Gervain [e], Ferenc Izbéki [e], Adrienn Halász [e], Dezső Kelemen [f], Richárd Szmola [g], János Novák [h], Stefan Crai [h], Anita Illés [i], Áron Vincze [i], Zsolt Molnár [j], Márta Varga [k], Barnabás Bod [l], Gyula Farkas Jr. [m], János Sümegi [n], Attila Szepes [o], Zsolt Dubravcsik [o], Natália Lásztity [p], Andrea Párniczky [p], es [r], Zsolt Szentkereszty [s], s Sahin-Tóth [d, 1], Jonas Rosendahl [b, 1], n Pancreatic Study Group

PLoS One. 2018 Nov 8;13(11):e0206869. doi: 10.1371/journal.pone.0206869. eCollection 2018.

The common truncation variant in pancreatic lipase related protein 2 (PNLIPRP2) is expressed poorly and does not alter risk for chronic pancreatitis.

Németh BC[1,2], Pesei ZG[1,2], Hegyi E[1,3], Szücs Á[4], Szentesi A[2,3], Hegyi P[3,5], Lowe ME[6], Sahin-Tóth M[1].

MDPI

A Common CCK-B Receptor Intronic Variant in Pancreatic Adenocarcinoma in a Hungarian Cohort

Anita Balázs, MD,
First Department of Medicine, University of Szeged, Szeged, Hungary

Article

Genetic Analysis of Human Chymotrypsin-Like Elastases 3A and 3B (CELA3A and CELA3B) to Assess the Role of Complex Formation between Proelastases and Procarboxypeptidases in Chronic Pancreatitis

Andrea Párniczky [1,†], Eszter Hegyi [1,†], Anna Zsófia Tóth [1], Ákos Szücs [2], Andrea Szentesi [3,4], Áron Vincze [5], Ferenc Izbéki [6], Balázs Csaba Németh [4], Péter Hegyi [3,4] and Miklós Sahin-Tóth [1,*]

'TAKE HOME MESSAGE'

1. Be sure that **establishing a registry is the best way** to answer your questions and reach your scientific goals
2. Incorporate the knowledge and experience of **international registries**
3. Be aware of the **benefits and pitfalls** of your registry
4. Build up a **disease specific biobank** (if feasible)

Thank you for your attention!

PRACTICE:

Registry Article Overview

Bálint Erőss
Pécs, Hungary

6 Question

6 Answers

Each group presents 1 Answer

1. What is the objective/hypothesis of the study?

2. Why is the question raised important (so what???)?

3. What are the major data sources? Can you judge how reliable they are?

4. What are the eligibility criteria? Would you add extra criteria or subtract any of them?

5. Why did use standardized incidence instead of raw incidence?

6. How long is the observation period? Does it impose any form of bias?

Thank you for your participation!